FEMALE INCONTINENCE PREVENTION DEVICE

FIELD OF INVENTION

The present invention relates generally to incontinence prevention devices, and more particularly to an incontinence prevention devices having a non-concentric retention structures.

BACKGROUND OF INVENTION

Many adults suffer urinary incontinence although urinary incontinence is more common in women than in men. The increased frequency in women is due primarily to the laxity of the bladder support structures resulting from pregnancy and aging. Surgical correction is possible in some cases, but surgery is invasive, costly and dangerous. Urethral incontinence prevention devices, such as for example catheters, plugs and other similar devices, in most cases offer a better solution but can be cumbersome to use, can be expelled during bowel movements, and are typically relatively expensive to manufacture.

There are a wide variety of incontinence prevention devices available, including: catheters that have lumen for urine to flow through; valved catheters; plugs that prevent the flow of urine until the plug is removed; and cylindrical supports against which the sphincter seals the urethra to prevent the flow of urine. Foley catheters are one type of commonly used catheter. Foley catheters are essentially elongated tubes. They are placed in the urethra to drain urine through the central lumen. An inflatable balloon is included near the distal end of the tube serves as a retention structure. When inflated, the balloon holds the catheter in place. The proximal end of a Foley catheter typically has two ports: a drainage port to drain urine from the bladder and a balloon inflation port to inflate and deflate the balloon. The drainage port creates a permanent opening between the bladder and outside environment. Because the bladder is continuously emptied, the bladder's dome continuously rests on the tip of the catheter above the retention balloon causing compression, irritation and erosion of tissue as well as other tissue problems. Therefore, a need exists for a retention structure that does not protrude into the bladder such that it contacts the bladder's dome.

Plugs totally block the flow of urine. Therefore, the plugs typically require removal for the user to urinate. After removal, the old plug is not sterile and a new sterile plug must inserted into the urethra Plugs' retention structures are typically cumbersome to operate and traumatic to the tissue. Thus, improper use can lead to irritation and infection from tissue traumatization. Further, the retention devices on the plugs are typically fluid filled and therefore relatively complex to manufacture. Therefore, a need exists for an incontinence prevention device that provides an atraumatic and simple means for insertion and removal and further reduces manufacturing costs.

Further, some urethral incontinence devices include open loop or pigtail type retention structures. These devices may be expelled when a user tenses the abdomen, such as when a user bears down during a bowel movement, because of a phenomenon called bladder neck drop often associated with incontinent female patients. With bladder neck drop, the bladder neck extends downward to encompass at least a portion of the urethra. The open loop type retention structures are thought to drop into the downward extension and thereafter could be entrapped in the urethra rendering it quasi-rectilinear as the bladder neck resumes its original

shape. The improperly positioned device no longer functions properly and the quasi-rectilinear bladder retention structure can no longer maintain the device at its proper location permitting the user to later expel the device. Therefore, a need exists for an incontinence prevention device having a retention structure that maintains its appropriate position within the bladder neck regardless the physical forces acting on it, and can recover after momentary bladder neck drop.

In addition, typical incontinence prevention devices require, at least to some extent, that a proximal end extend from the urethral meatus. The proximal ends tend to scatter urine droplets during urination. The scattering of urine is inconvenient and unsanitary. Therefore, a need exists for a catheter that permits a directed stream of urine.

The present invention meet these needs and provides additional improvements and advantages that will be recognized by those skilled in the art upon review of the following description and figures.

SUMMARY OF THE INVENTION

The present invention further provides an incontinence prevention device that is simple and inexpensive to construct and easy to use. The incontinence prevention device of the present invention includes a shaft and a retention structure. The retention structure is configured as a closed loop non-concentrically disposed about a longitudinal axis of the shaft. The retention structure's closed loop tends to maintain the incontinence prevention device within the bladder neck. The retention structure's non-concentrically orientation accounts for the bladder's asymmetry. The retention structure may further include a protuberance projecting from the retention structure. The protuberance may project from a midpoint of the closed loop. The shaft may further include a lumen configured to receive a stylet. The lumen is typically coextensive with the shaft and substantially coextensive with the retention structure. In addition, the lumen may be coextensive with the protuberance. The device may also include a hydrogel coating disposed on its outer surface. The shaft may include an orientation marking at its proximal end. The proximal end of the shaft may also have a beveled edge to prevent the spraying of urine during urination. A segment of the retention structure may additionally define a cavity to receive another portion of the retention structure to further reduce the diameter for insertion. For insertion, the retention structure is rendered substantially rectilinear. A stylet may be provided to insert into a lumen in the device to render the retention structure substantially rectilinear. Once rectilinear, the device is inserted into the urethra so that the retention structure is placed within the bladder. Once in the bladder, the retention structure is reformed into a loop. The retention structure is then positioned adjacent the neck of the bladder with the non-concentrically disposed retention structure in a predetermined orientation

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a perspective view of a urethral catheter showing a first embodiment of the retention mechanism;

FIG. 2 illustrates a left end view of the urethral catheter of FIG. 1;

FIG. 3 illustrates a perspective view of a urethral catheter showing a second embodiment of the retention mechanism;

FIG. 5A illustrates a side view of a stylet;

FIG. 5B illustrates a side view urethral catheter of FIG. 1 with a stylet partially inserted into the urethra measuring device; and

FIG. 5C illustrates a side view urethral catheter of FIG. 1 with a stylet fully inserted into the urethra measuring device.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is applicable to a variety of devices that are maintained in the urethra The invention is described in the context of an incontinence device for a woman's urethra for exemplary purposes. The appended claims are not intended to be limited to any specific example or embodiment described in this specification. It will be understood by those skilled in the art that the present invention may be used in related medical applications including but not limited to incontinence prevention devices, obstruction relief devices, drainage devices; or other similar devices which require retention in a lumen. Further, in the drawings described below, the reference numerals are generally repeated where identical elements appear in more than one figure.

FIG. **1** illustrates an embodiment of an incontinence prevention device **10** in accordance with the present invention. Device **10** includes a shaft **12**, a retention structure **14** and a proximal retention structure **15**. Device **10** may further includes a lumen **18**, shown in FIG. **2**. Device **10** is typically circular in cross-section although other shapes such as oval that allow the sphincter to sealably contract against the catheter's outer surface may also be used. Device **10** is typically composed of a flexible biocompatible material such as silicone, silastic, polyurethane, polyethylene, polyimide, PTFE, ETFE, or other materials or combinations of materials known to those skilled in the art. Typically, the material used has a durometer shore hardness of between about 30 and 95 shore A. In addition, device **10** may be coated with a lubricious material, such as a bydrogel, to allow for easier insertion and reduced irritation.

Shaft **12** is typically configured as a semi-rigid region of device **10** typically having a shape suitable for placement in the urethra Shaft **12** is further configured to have sufficient rigidity for sphincter muscles to contract against it so as to substantially stop the flow of urine from a user's bladder. Shaft **12** may also include an orientation marking **38**, shown in FIGS. **5B** and **5C** and discussed below. The orientation marking may either be visible, for example a line or dot, or tactile, for example a crevice or dimple. Shaft **12** typically has a diameter of around 8 French to correspond with an appropriate size for insertion in an adult female's urethra. The device can be made with various other diameters ranging from between about 5 to 16 French to enable the proper sizing to accommodate the range of urethral sizes. The shaft typically has a length of between about 3.5 to 4.5 centimeters enabling the proper sizing of the catheter's length for most women's urethras. The proximal end includes a proximal retention structure **15**. Proximal retention structure **15** generally functions to prevent the incontinence prevention device from moving up into the urethra and provides a means for gripping the incontinence prevention device during removal. Proximal retention structure **15** is typically configured to conform to the vestibule proximate the urethral opening. The proximal end of the shaft may also include a beveled edge **16**. Beveled edge **16** tends to prevent the spraying of urine during urination. In addition, the proximal end typically includes a structure for preventing the incontinence prevention device from tracking up the urethra.

Retention structure **14** comprises a closed loop at the distal end of the shaft non-concentrically disposed about shaft **12**. Retention structure **14** may be integral with shaft **12** or a separate element that is secured to shaft **12**. FIG. **2** shows a proximal end view of device **10** of FIG. **1** illustrating an embodiment of the non-concentric relationship of shaft **12** to retention structure **14**. Retention structure **14** projects in a general lateral direction from the shaft and is typically non-concentrically disposed about shaft **12**. Retention structure **14** is typically shaped to be received at the base of the urinary bladder and above the bladder's neck. Retention structure **14** maintains the incontinence prevention device in position as the bladder neck rises and drops with patient activity. The retention structure is thought to be maintained within the bladder as a moist watermelon seed is ejected when squeezed between one's thumb and forefinger. Thus, when the retention structure slips below the neck and into the urethra, there is a tendency for the retention structure to be forced back into the bladder as the bladder neck and/or urethra resume their original orientation. Typically, a device having a retention structure in accordance with the present invention is capable of maintaining the catheter's position regardless of the forces typically encountered. However, the device may be removed by simply pulling on the proximal end with sufficient force to collapse the retention structure.

The retention structure may be substantially circular, as shown in FIG. **2**, or may have various shapes appropriate for holding device **10** within the urethra that will be recognized by those skilled in the art. The retention structure is configured to be collapsible for insertion through the urethra and to regain its shape after insertion once in the bladder. After insertion, the retention structure has sufficient rigidity to hold the retention structure within the urinary bladder. To retain its shape, the retention structure may include an internal wire or be composed of a material with sufficient memory to regain the loop configuration.

In addition, FIG. **2** shows lumen **18** extending through the proximal end of shaft **12**.

FIG. **3** shows an alternative embodiment of the retention structure. In the embodiment of FIG. **3**, retention structure **14** includes a protuberance **22** projecting from the loop. In addition and as discussed in more detail below, a segment **21** may be attached to shaft **12** to form the loop and to provide protuberance **22**. Protuberance **22** forms a smaller leading tip for easier insertion and helps to maintain the incontinence prevention device on a stylet during insertion. To facilitate this, protuberance **22** typically includes a lumen that is coextensive with lumen **18** of shaft **12**. That is, lumen **18** extends from a proximal end incontinence prevention device **10** to a distal end **26**. Typically, the lumen does not extend through distal end **26** but only to a point immediately proximal to distal end **26**. This configuration prevents the flow of urine through the lumen. Alternatively, the incontinence prevention device may have the lumen extending through distal end **26** to allow fluid flow through the lumen as required for some applications. When the retention structure includes a portion of the shaft, a segment **21** is typically provided to complete the loop comprising retention structure **15**. Segment **21** is typically attached at one end to a first location proximate to distal end **26** of shaft **12** and, at the segment's other end, to a second location along the shaft closer to the shaft's proximal end so as to form a loop. Typically, the length of segment **21** and the positions for its attachment are selected so as to permit the loop to assume an appropriate configuration for insertion into the urethra and subsequent reformation into a loop when in the bladder.

Shaft **12** and segment **21** may be configured to appear as a single unit for insertion. That is, when you straighten out